

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/)
FENFLURAMINE/DEXFENFLURAMINE)) MDL NO. 1203
PRODUCTS LIABILITY LITIGATION)

THIS DOCUMENT RELATES TO:)
)
SHEILA BROWN, et al.)
)
v.)
)
AMERICAN HOME PRODUCTS)
CORPORATION) NO. 99-20593

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 8443

Bartle, C.J.

March 29, 2010

Peter H. Berg ("Mr. Berg" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,¹ seeks benefits from the AHP Settlement Trust ("Trust"). Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support his claim for Matrix Compensation Benefits ("Matrix Benefits").²

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1
(continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In August, 2002, claimant submitted a completed Green Form to the Trust signed by his attesting physician, Michael E. Robertello, M.D., F.A.C.C. Based on an echocardiogram dated April 5, 2002, Dr. Robertello attested in Part II of Mr. Berg's Green Form that claimant had severe aortic regurgitation.³ Based

2. (...continued)
describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these diet drugs.

3. Dr. Robertello also attested that claimant had mild mitral regurgitation, mitral annular calcification, a reduced ejection fraction in the range of 50% to 60%, and New York Heart Association Functional Class II symptoms. These conditions, however, are not at issue in this claim.

on such findings, claimant would be entitled to Matrix B-1,⁴ Level I⁵ benefits in the amount of \$7,841.⁶

In the report of claimant's echocardiogram, the reviewing cardiologist, Bartholomew J. Bonazinga, M.D., F.A.C.C., noted that the study demonstrated severe aortic regurgitation. Specifically, Dr. Bonazinga explained:

Color wave doppler study of the aortic valve suggests severe aortic insufficiency. The regurgitant jet is at least 50% of the width of the outflow track. This is confirmed in the four-chamber and five-chamber views as well. The regurgitant jet reaches into the central portion of the left ventricle as well.⁷

4. In Part I of his Green Form, claimant requested benefits on Matrix A. Upon review of claimant's Green Form and supporting materials, the Trust determined that claimant was eligible only for benefits on Matrix B because he ingested Diet Drugs for 60 days or less. Although claimant contested this determination in his response to the Trust's statement of the case, a dispute as to proof of ingestion is not properly raised in response to an Order to show cause. See Pretrial Order ("PTO") No. 2807 (Mar. 26, 2003), Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), Rule 18(e). In any event, the pharmacy records Mr. Berg submitted do not establish that he ingested Diet Drugs for more than sixty days.

5. In Part I of his Green Form, claimant requested Matrix benefits at Level V. Upon review of claimant's Green Form and supporting materials, the Trust determined, and claimant did not dispute, that Mr. Berg alleged conditions consistent with a claim for Level I benefits.

6. Under the Settlement Agreement, a claimant is entitled to Level I benefits for damage to the aortic valve if he or she is diagnosed with severe aortic regurgitation and no complicating factors. See Settlement Agreement § IV.B.2.c.(1).

7. Dr. Robertello also performed a second review of claimant's echocardiogram. In his report, Dr. Robertello observed that claimant had "[s]evere aortic insufficiency by color flow."

Under the definition set forth in the Settlement Agreement, severe aortic regurgitation is present where the regurgitant jet height ("JH") in the parasternal long-axis view (or in the apical long-axis view if the parasternal long-axis view is unavailable) is greater than 49% of the left ventricular outflow tract height ("LVOTH"). See Settlement Agreement §§ I.22 & IV.B.2.c.(1)(a).

In December, 2003, the Trust forwarded the claim for review by Zia Kidwai, M.D., F.A.C.C., F.A.S.E., one of its auditing cardiologists. In audit, Dr. Kidwai concluded that claimant had moderate aortic regurgitation and that there was no reasonable medical basis for Dr. Robertello's representation that claimant had severe aortic regurgitation. In support of this conclusion, Dr. Kidwai explained that "[t]here is an eccentric jet of [aortic insufficiency]. The proximal jet width does not reach 50% of the [left ventricle]."

Based on Dr. Kidwai's finding that claimant had moderate aortic regurgitation, the Trust issued a post-audit determination denying Mr. Berg's claim. Pursuant to the Audit Rules, claimant contested this adverse determination.⁸ In contest, claimant submitted a letter from Dr. Robertello wherein Dr. Robertello stated, in relevant part, that: (1) he reviewed

8. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in PTO No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807. There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Mr. Berg's claim.

the echocardiogram and determined that Mr. Berg suffered from severe aortic regurgitation; and (2) regardless of the level of Mr. Berg's aortic regurgitation, it likely was caused by his ingestion of Diet Drugs. Claimant also submitted a letter from Dr. Bonazinga, who stated, among other things, that he "disagree[d] completely with [Dr. Kidwai's] evaluation of this Echo Doppler, which although technically not perfect ... clearly shows moderate aortic insufficiency in at least these two views."

The Trust then issued a final post-audit determination, again denying Mr. Berg's claim. Claimant disputed this adverse determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Mr. Berg's claim should be paid. On January 13, 2005, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 4376 (Jan. 13, 2005).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on July 1, 2005, and claimant submitted a sur-reply on July 18, 2005. Under the Audit Rules, it is within the Special Master's discretion to appoint a

Technical Advisor⁹ to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant, and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met his burden in proving that there is a reasonable medical basis for the attesting physician's finding that he had severe aortic regurgitation. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

9. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. U.S., 863 F.2d 149, 158 (1st Cir. 1988). In cases, such as here, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

In support of his claim, claimant asserts that "[t]o the extent that Dr. Kidwai made any findings that dispute Dr. Bonazinga's findings, all of Dr. Kidwai's findings are wrong and all of Dr. Bonazinga's findings are correct and have a reasonable medical basis."¹⁰ Mr. Berg also argues that he went to Dr. Bonazinga because Dr. Bonazinga participated in the Trust's Screening Program.¹¹ Finally, Mr. Berg suggests that Dr. Bonazinga's findings are correct because he was able to evaluate the echocardiogram tape, while Dr. Kidwai indicated that the tape was not evaluable.¹²

In response, the Trust asserts that claimant has failed to establish a reasonable medical basis for his claim because he "does not rebut the findings of Dr. Kidwai. Instead, [claimant] merely argues that the findings of his Attesting and Reviewing Physicians are correct, while the findings of Dr. Kidwai are incorrect." The Trust also asserts that Dr. Bonazinga's participation in the Screening Program does not entitle his opinion to any additional weight.¹³

10. Claimant incorrectly refers to Dr. Bonazinga, rather than Dr. Robertello, as the attesting physician.

11. See Settlement Agreement § IV.A.1 (Screening Program established under the Settlement Agreement).

12. Contrary to claimant's argument, in the Report Of Auditing Cardiologist Opinions Concerning Green Form Questions At Issue, Dr. Kidwai responded "No" to a question as to whether the echocardiogram tape was not evaluable, indicating that he was able to evaluate the echocardiogram tape.

13. In his sur-reply, claimant addresses only the length of his
(continued...)

The Technical Advisor, Dr. Vigilante, reviewed claimant's echocardiogram and determined that claimant had moderate aortic regurgitation and that there was no reasonable medical basis for finding that Mr. Berg had severe aortic regurgitation. Specifically, Dr. Vigilante stated, in pertinent part, that "[m]oderate aortic regurgitation was present. This was an eccentric jet traveling immediately underneath the anterior mitral leaflet into the left ventricle. The JH/LVOTH was less than 40% in all views."

In response to the Technical Advisor Report, claimant argues that Dr. Vigilante has not provided a curriculum vitae on which he can "assess his bona fides as an expert cardiologist." Claimant also argues that his "inability to confront [Dr. Vigilante] and to challenge his findings in this procedure violates due process." Finally, claimant argues that Dr. Vigilante's "conclusions are unsupported by any medical analysis and should be disregarded."

After reviewing the entire Show Cause Record, we find claimant's arguments are without merit. First, and of crucial importance, claimant does not adequately contest the findings of moderate aortic regurgitation offered by Dr. Kidwai and Dr. Vigilante. Specifically, Dr. Kidwai concluded that the "eccentric jet of [aortic insufficiency] ... does not reach 50% of the [LVOTH].". Similarly, Dr. Vigilante observed that

13. (...continued)
ingestion of Diet Drugs.

"[m]oderate aortic regurgitation was present. This was an eccentric jet traveling immediately underneath the anterior mitral leaflet into the left ventricle. The JH/LVOTH was less than 40% in all views."¹⁴ Rather than refute or respond to Dr. Kidwai's and Dr. Vigilante's specific conclusions, Mr. Berg states only that their conclusions are incorrect. In addition, Dr. Robertello does not explain why his interpretation is correct. Moreover, Dr. Bonazinga, following a second review of claimant's echocardiogram, confirmed that the level of aortic regurgitation seen on Mr. Berg's echocardiogram was only moderate. As stated by Dr. Bonazinga:

At index #4255 there is clearly moderate aortic insufficiency noted in a low parasternal view, which is technically difficult but obvious. There is a second area on the tape that shows moderate aortic insufficiency with a regurgitant jet covering 50% of the outflow tract at index # 4597.

I disagree completely with the other physician's evaluation of this Echo Doppler, which although technically not perfect it clearly shows moderate aortic insufficiency in at least these two views. I recommend that a third physician look at this tape because it clearly does show a significant aortic insufficiency jet covering at least 40-50% of the outflow tract.

Although Dr. Bonazinga noted that claimant's aortic insufficiency covers up to 50% of the LVOTH, Dr. Bonazinga characterizes the regurgitation as moderate, a conclusion confirmed by both the

14. For this reason as well, we reject claimant's argument that Dr. Vigilante did not support his conclusions with medical analysis.

auditing cardiologist and the Technical Advisor. On this basis alone, claimant has failed to meet his burden in proving that there is a reasonable medical basis for his claim.

Further, to the extent claimant relies on Dr. Robertello's opinion that the aortic regurgitation was caused by his ingestion of Diet Drugs, such reliance is misplaced. Causation is not at issue in resolving Mr. Berg's claim for Matrix Benefits. Rather, claimant is required to show that he meets the objective criteria set forth in the Settlement Agreement. As we previously concluded:

Class members do not have to demonstrate that their injuries were caused by ingestion of Pondimin and Redux in order to recover Matrix Compensation Benefits. Rather, the Matrices represent an objective system of compensation whereby claimants need only prove that they meet objective criteria to determine which matrix is applicable, which matrix level they qualify for and the age at which that qualification occurred....

PTO No. 1415 at 51 (Aug. 28, 2000). In addition, we noted that:

... [I]ndividual issues relating to causation, injury and damage also disappear because the settlement's objective criteria provide for an objective scheme of compensation.

Id. at 97. The Settlement Agreement clearly and unequivocally requires a claimant to prove that he or she suffers from severe aortic regurgitation to receive Level I benefits for damage to the aortic valve. We must apply the Settlement Agreement as written. Accordingly, Mr. Berg's assertion that the cause of his

aortic regurgitation was his ingestion of Diet Drugs is irrelevant to the issue before the court.

In addition, we reject claimant's assertion that he is entitled to Matrix Benefits because the echocardiogram that forms the basis of his claim for Matrix Benefits was conducted by a cardiologist who participated in the Screening Program for Fund A Benefits under the Settlement Agreement. See Settlement Agreement § IV.A. The Settlement Agreement clearly provides that the sole benefit that a class member is entitled to receive for a favorable echocardiogram under the Screening Program is a limited amount of medical services or a limited cash payment:

All Diet Drug Recipients in Subclass 2(b) and those Diet Drug Recipients in Subclass 1(b) who have been diagnosed by a Qualified Physician as FDA Positive by an Echocardiogram performed between the commencement of Diet Drug use and the end of the Screening Period, will be entitled to receive, at the Class Member's election, either (i) valve-related medical services up to \$10,000 in value to be provided by the Trust; or (ii) \$6,000 in cash.

Id. § IV.A.1.c. Thus, by the plain terms of the Settlement Agreement, a Screening Program echocardiogram does not automatically entitle a claimant to Matrix Benefits.

Indeed, this conclusion is confirmed by the Settlement Agreement provisions concerning claimants eligible for Matrix Benefits. Specifically, claimants with a diagnosis of FDA Positive or mild mitral regurgitation merely become eligible to seek Matrix Benefits. See id. § IV.B.1. Further, adopting claimant's position would be inconsistent with Section VI.E. of

the Settlement Agreement, which governs the audit of claims for Matrix Benefits, as well as this Court's decision in PTO No. 2662 (Nov. 26, 2002), which mandated a 100% audit requirement for all claims for Matrix Benefits. See, e.g., PTO No. 2662 at 13. As nothing in the Settlement Agreement supports the conclusion that a favorable Screening Program echocardiogram for purposes of Fund A Benefits results in an immediate entitlement to Matrix Benefits, we decline claimant's request to interpret the Settlement Agreement in this fashion.

We also disagree with claimant that the Technical Advisor must provide a curriculum vitae. As we previously explained:

Court-appointed Technical Advisors are not experts subject to the Federal Rules of Evidence.... "Throughout its text, Fed. R. Evid. 706 refers not to 'experts' generally, but to a more exclusive class: 'expert witnesses.' Because the plain language of a Civil Rule is the most reliable indicator of its meaning, we are constrained to conclude that the grasp of Rule 706 is confined to court-appointed expert witnesses; the rule does not embrace expert advisors or consultants."

PTO No. 6824 at 9 n.15 (Dec. 29, 2006) (quoting Reilly, 863 F.2d at 155) (further citation omitted).

Finally, claimant's argument that he has been deprived of due process because he is not permitted to confront and challenge the Technical Advisor is without merit. It is claimant's burden in the show cause process to show why he is entitled to Matrix Benefits. See Audit Rule 24. The audit and

show cause process, as approved by this court, complies with due process requirements as claimant has had notice and an opportunity to present his evidence in support of his claim and to respond to the Technical Advisor Report.

For the foregoing reasons, we conclude that claimant has not met his burden of proving that there is a reasonable medical basis for finding that he had severe aortic regurgitation. Therefore, we will affirm the Trust's denial of Mr. Berg's claim for Matrix Benefits.